Remarks

The applicant and his representatives have fully considered the Office Action of September 11, 2003. In response thereto, the applicant has amended claim 1 to more clearly define the invention. Claims 4 and 6 have been amended to overcome 35 U.S.C. § 112, ¶2 rejections. Claims 2 and 5 have been amended to more clearly define the invention. Claim 7 has been cancelled. Therefore, claims 1-6 are pending in the application.

More specifically, claim 1 has been amended to positively and more clearly recite the method steps of providing a stent-graft having dilation restriction means for restricting dilation of the stent-graft beyond a maximum diameter which maximum diameter is greater than the vessel diameter into which the stent-graft will be deployed, and then trimming the stent-graft to a length that is greater than the length of the aneurysm when the stent-graft is dilated to its maximum diameter. This method is neither disclosed nor suggested in any prior art, and is directed to solving the problem of stent-graft dislodgment. The applicant believes that as amended, claim 1 now more clearly recites the novel features of the present method.

For the reasons set forth below, the applicant submits that all rejections have been overcome and respectfully requests reexamination in light thereof and notice of allowance.

Oath/Declaration

Despite it being evident that the Inventor made his address change at the time of executing the oath/declaration, the document has been re-executed with the corrected address. The supplemental oath/declaration as corrected is enclosed. Withdrawal of this rejection is requested.

Specification

Title

The Title has been amended at the request of the Examiner. The applicant believes, however, that the prior title is descriptive because the invention is directed to a method of preventing the dislodgment of a stent-graft. In fact, and as will be discussed in more detail below, the present invention is concerned not only with immediate treatment of an aneurysm, but also with solving the problems associated with dislodgment caused by subsequent dilation

of the stent-graft (and its subsequent shortening) over time due to body changes. Furthermore, it is noted that this invention is a method of treating an aneurysm which is based on the correlation between the maximum dilation as limited by the claimed restriction means and the minimum length to which the stent-graft is thereby allowed to reach over time. This was the basis of the earlier title, and the applicant has attempted to make this method more clear in amended claim 1 (discussed in detail below).

Other

The continuing data has been updated. Withdrawal of this rejection is respectfully requested.

Reference to Figures 19 and 20 has been cancelled and related text has been amended. No new matter was added. Withdrawal of this rejection is respectfully requested.

35 U.S.C. § 112, ¶2

Claims 4, 6, and 7 were rejected under 35 U.S.C. § 112, ¶2. Claim 7 has been cancelled. Claims 4 and 6 have been amended to obviate this rejection. Withdrawal of all 35 U.S.C. § 112, ¶2 rejections is therefore respectfully requested.

35 U.S.C. § 103

Claims 1-6 stand rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 4,140,120 to Choudhury (Choudhury) in view of U.S. Patent No. 5,483,158 to Lenker et al. (Lenker). The applicant respectfully submits that claim 1 as amended recites limitations neither taught nor suggested in either reference, alone or combined, and for the reasons set forth below, respectfully submits that claims 1-6 are patentable as amended. More specifically, the applicant respectfully submits that even if the two references are combined, one does not get the present invention.

Choudhury

Choudhury is directed to a method and article for performing an aneurysm repair. Specifically, Choudhury is a method for permanently anchoring a stent within a vessel and relies in part on using a stent which has an outside diameter when fully expanded which is

slightly larger than the inside diameter of the vessel in need of repair. To the extent Choudhury addresses stent selection or dimensions, it is only concerned with determining the maximum diameter of the stent.

Lenker

Lenker is relied upon in the Office Action for its teaching of the presence of reinforcement elements on a stent-graft. Lenker, however, is concerned with preventing the formation of bulges formed by uneven expansion of a liner material during deployment or size adjustment. See Column 2, lines 37-40. In order to achieve this objective, Lenker teaches a stent-graft having reinforcement elements to allow a controlled, selective expansion of portions of the stent to promote anchoring or sealing, but which would resist stent-graft expansion in alternative portions, particularly adjacent a weakened portion of a body lumen.

The Present Invention

The present invention, unlike anything taught or suggested in any known prior art, is directed to a method of preventing dislodgment over a long period of time. This is accomplished in the claimed method by providing a stent-graft having dilation restriction means for restricting dilation of the stent-graft beyond a maximum diameter which maximum diameter is greater than the vessel diameter into which the stent-graft will be deployed, and then trimming the stent-graft to a length that is greater than the length of the aneurysm when the stent-graft is dilated to its maximum diameter. This claimed method insures that the stent-graft will not later shorten to a length less than the aneurysm and thereby dislodge. This method is neither disclosed nor suggested in any prior art.

Specifically, neither Lenker nor Choudhury teach a method of preventing dislodgment over time. Moreover, neither reference addresses controlling expansion to prevent a decrease in length and subsequent dislodgment. Lenker merely provides an apparatus for restricting expansion of the graft by incorporating expansion limiting belts or rings. Lenker is silent on providing a stent-graft having dilation restriction means for restricting dilation of the stent-graft beyond a maximum diameter which maximum diameter is greater than the vessel diameter into which the stent-graft will be deployed, and then trimming the stent-graft to a length that is greater than the length of the aneurysm when the stent-graft is dilated to its maximum diameter. This method is neither disclosed nor suggested in any prior art.

The Office Action indicated that one skilled in the art would have been motivated to utilize the Lenker device in Choudhury's method. Even if this was true, the presently claimed method is not taught or suggested through their combination. Specifically, Choudhury teaches a device having a wire which pushes against expansion rings causing convolutions to move apart and form a singular ring or larger diameter. Choudhury merely recognizes that the outside diameter of the stent when fully expanded should be slightly larger than the inside diameter of the vessel, but is silent regarding any maximum stent diameter or related stent-graft shortening. The device of Choudhury contributes to the very problem solved by the presently claimed method.

Similarly lacking in a suggestion or teaching of the presently claimed method, Lenker teaches a restriction mechanism for preventing the expansion of a graft beyond a particular diameter. Important, however, is that Lenker is silent regarding any teaching of restricting dilation beyond a catastrophic diameter. Thus, Lenker's disclosure is completely devoid of any recognition, much less a solution, of the problems solved by the presently claimed method.

More specifically, the position expressed in the Office Action appears to be that because Lenker recognizes the desirability of having a dilation restriction means to prevent aneurysms from forming in the prosthesis and bulges which may lead to folds of the liner material leading to leakage between the prosthesis and the vessel wall, it would have been obvious to provide a stent-graft having dilation restriction means for restricting dilation of the stent-graft beyond a maximum diameter which maximum diameter is greater than the vessel diameter into which the stent-graft will be deployed, and then trimming the stent-graft to a length that is greater than the length of the aneurysm when the stent-graft is dilated to its maximum diameter. This position is not based in established CAFC law.

Moreover, there is simply no reason, other than by using hindsight gleaned from the claimed invention itself, to see the presently claimed method as a mere combination of the apparati of Choudhury and Lenker. For these reasons, the applicant respectfully submits that claims 1-6 are in condition for allowance. Early and favorable notification to this effect is respectfully requested.

Respectfully submitted,

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Encls.: Supplemental Declaration & Power of Attorney

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